CHAPTER He-P 4000

PART He-P 4030 LICENSING OF RADIOACTIVE MATERIAL

REVISION NOTE:

Doc. #6942, effective 2-1-99, repealed Parts He-P 2030, 2031, 2032, 2033, 2034, 2035, 2042 and 2093 relative to Radiation and Radioactive Material and adopted new rules to replace them and renumbered them as He-P 4030, 4031, 4032, 4033, 4034, 4035, 4093 and 4096.

He-P 4030.01 Requirements.

(a) No person shall receive, possess, use, transfer, own, or acquire radioactive materials, except as authorized pursuant to a license issued by the DHHS/BRH, or as otherwise provided in this Chapter.

(b) In addition to the requirements of He-P 4030:

(1) All licensees are subject to the requirements of He-P 4001 through He-P 4003, He-P 4019 through He-P 4023 and He-P 4037;

(2) Licensees engaged in industrial radiographic operations are subject to the requirements of He-P 4034;

(3) Licensees using radionuclides in the healing arts are subject to the requirements of He-P 4035;

(4) Licensees engaged in land disposal of radioactive material are subject to the requirements of He-P 4060 through 4064;

(5) Licensees engaged in wireline and subsurface tracer studies are subject to the requirements of He-P 4039;

(6) Licensees engaged in the manufacture or transfer of certain items containing radioactive material are subject to He-P 4032;

(7) Licensees of broad scope other than human use are subject to He-P 4033; and

(8) General licenses are subject to He-P 4031.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99

He-P 4030.02 Exemptions, Source Material.

(a) Any person shall be exempt from He-P 4030 to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.

(b) Any person shall be exempt from He-P 4030 to the extent that such person receives, possesses,

uses, or transfers unrefined and unprocessed ore containing source material.

(c) Any person shall be exempt from He-P 4030 to the extent that such person receives, possesses, uses, or transfers:

(1) Any quantities of thorium contained in:

a. Incandescent gas mantles; or

b. Vacuum tubes; or

c. Welding rods; or

d. Electric lamps for illuminating purposes provided that each lamp shall not contain more than 50 milligrams of thorium; or

e. Germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp shall not contain more than 2 grams of thorium; or

f. Rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these; or

g. Personnel neutron dosimeters, provided that each dosimeter shall not contain more than 50 milligrams of thorium.

(2) Source material contained in the following products:

a. Glazed ceramic tableware, provided that the glaze shall not contain more than 20 percent by weight source material; or

b. Glassware, containing not more than 10 percent by weight source material, but not including glass enamel or ceramic used in construction; or

c. Piezoelectric ceramic containing not more than 2 percent by weight source material; or

d. Glass enamel or glass enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983.

(3) Photographic film, negatives, and prints containing uranium or thorium;

(4) Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy shall not exceed 4 percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;

(5) Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:

a. The counterweights are manufactured in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, authorizing distribution by the licensee pursuant to 10 CFR Part 40;

b. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM";

c. Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED";

d. This exemption shall not authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering; and

e. Counterweights manufactured prior to December 31, 1969, the requirements specified in He-P 4030.02(c)(5)c. and d. shall be met if such counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM".

(6) Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

a. The shipping container is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM"; and

b. The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of 1/8 inch (3.2 mm).

(7) Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and does not include:

a. The shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens; or

b. The receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

(8) Uranium contained in detector heads for use in fire detection units, provided that each detector head shall contain not more than 0.005 microcurie of uranium; or

(9) Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

a. The thorium shall be dispersed in the nickel-thoria alloy in the form of finely divided thoria such as thorium dioxide; and

b. The thorium content in the nickel-thoria alloy shall not exceed 4 percent by weight.

(d) The exemptions in He-P 4030.02(c) shall not authorize the manufacture of any of the products described.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99

He-P 4030.03 Exemptions, Radioactive Materials Other Than Source Materials.

(a) Except as provided in He-P 4030.03(b), any person shall be exempt from He-P 4030 to the extent that such person receives, possesses, uses, transfers, owns, or acquires products or materials containing radioactive material in concentrations not in excess of those listed in He-P 4093.

(b) No person shall introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under He-P 4030.03(a) or equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or Licensing State except in accordance with a license issued pursuant to He-P 4032.04 or a general license issued pursuant to He-P 4030.18.

(c) Except for persons who apply radioactive material, or persons who incorporate radioactive material into, the following products, any person shall be exempt from this chapter to the extent that they receive, possess, use, transfer, own, or acquire the following products:

(1) Timepieces or hands or dials of timepieces which shall contain not more than the following specified quantities of radioactive material and which shall not exceed the following specified levels of radiation:

a. 25 millicuries of tritium per timepiece;

b. 5 millicuries of tritium per hand;

c. 15 millicuries of tritium per dial to include bezels when used;

d. 100 microcuries of promethium 147 per watch or 200 microcuries of promethium 147 per any other timepiece;

e. 20 microcuries of promethium 147 per watch hand or 40 microcuries of promethium 147 per other timepiece hand;

f. 60 microcuries of promethium 147 per watch dial or 120 microcuries of promethium 147 per other timepiece dial to include bezels when used; and

g. The levels of radiation from hands and dials containing promethium 147 shall not exceed, when measured through 50 milligrams per square centimeter of absorber:

1. For wrist watches, 0.1 milliard per hour at 10 centimeters from any surface;

2. For pocket watches, 0.1 milliard per hour at 1 centimeter from any surface;

3. For any other timepiece, 0.2 milliard per hour at 10 centimeters from any surface.

(2) Radium dial timepieces -- timepieces or timepiece hands or dials which shall contain not

more than the following specified quantities of radium and shall meet the following expressed conditions:

a. 0.15 microcurie of radium per watch;

b. 0.03 microcurie of radium per watch hand;

c. 0.09 microcurie of radium per watch dial;

d. 0.20 microcurie of radium per clock;

e. 0.04 microcurie of radium per clock hand;

f. 0.12 microcurie of radium per clock dial;

g. The timepiece is not a pocket watch;

h. Timepieces or timepiece hands or dials containing radium which were manufactured prior to the effective date of these rules;

i. The timepiece is marked or coded to identify the date of manufacture and that it contains radium; and

j. The timepiece emits sufficient luminosity, omitting photoactivation, that its dial can be read in the dark during its entire design lifetime.

(3) Lock illuminators containing not more than 15 millicuries of tritium or not more than 2 millicuries of promethium 147 installed in automobile locks so that the levels of radiation from each lock illuminator containing promethium 147 does not exceed 1 milliard per hour at 1 centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.

(4) Precision balances containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part.

(5) Automobile shift quadrants containing not more than 25 millicuries of tritium.

(6) Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas.

(7) Thermostat dials and pointers containing not more than 25 millicuries of tritium per thermostat.

(8) Electron tubes, provided that:

a. Each tube shall not contain more than one of the following specified quantities of radioactive material:

1. 150 millicuries of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electron tube;

2. 1 microcurie of cobalt 60;

3. 5 microcuries of nickel 63;

4. 30 microcuries of krypton 85;

5. 5 microcuries of cesium 137; and

6. 30 microcuries of promethium 147.

b. The level of radiation due to radioactive material contained in each electron tube, spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents shall not exceed 1 milliard per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeter of absorber.

(9) Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material provided that:

a. Each source shall contain no more than one exempt quantity set forth in He-P 4096;

b. Each instrument shall contain no more than 10 exempt quantities;

c. For purposes of He-P 4030.03(c)(9)b., an instrument's source(s) may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in He-P 4096, provided that the sum of such fractions shall not exceed unity;

d. For purposes of He-P 4030.03(c)(9)b., 0.05 microcurie of americium-241 shall be considered an exempt quantity under He-P 4096.

(10) Spark gap irradiators containing not more than 1 microcurie of cobalt 60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least 3 gallons (11.4 liters) per hour.

(d) Any person shall be exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium 46 which are designed for sand consolidation in oil wells, provided that:

(1) Such resins shall have been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, or shall have been manufactured in accordance with the specifications contained in a specific license or equivalent licensing document issued by the DHHS/BRH, any agreement state or to the manufacturer of such resins pursuant to licensing requirements equivalent to those in Section 32.16 and 32.17 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission; and

(2) This exemption shall not authorize the manufacture of any resins containing scandium 46.

(e) Except for persons who manufacture, process, or produce gas and aerosol detectors, any person shall be exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires:

(1) Radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, provided that detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.26 of 10 CFR Part 32.

(2) Naturally occurring material in gas and aerosol detectors designed to protect life or property from fire and airborne hazards provided that detectors containing naturally occurring material shall have been manufactured, imported, or transferred in accordance with a specific license issued by an Agreement State pursuant to equivalent conditions as in Section 32.26 of 10 CFR part 32.

(f) Except for persons who manufacture, process, or produce self-luminous products, any person shall be exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires:

(1) Tritium, Krypton 85, or Promethium 147 in self-luminous products manufactured, processed, imported, or transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR part 32.

(2) Naturally occurring material in self-luminous products manufactured, processed, imported, or transferred in accordance with a specific license issued by an Agreement State or Licensing State pursuant to equivalent conditions as in Section 32.22 of 10 CFR part 32.

(g) The exemptions in He-P 4030.03(f) shall not apply to Tritium, Krypton 85, Promethium 147, or naturally occurring material used in products for frivolous purposes or in toys or ornaments.

(h) Except as provided in He-P 4030.03(j) and (k), any person shall be exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in He-P 4096.

(i) Any person who possesses radioactive material received or acquired under the general license formerly provided in He-P 2031 shall be exempt from the requirements for a license set forth in He-P 4030 to the extent that such person possesses, uses, transfers or owns such radioactive material.

(j) The provisions of He-P 4030.03(h) and (i) shall not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

(k) No person shall, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in He-P 4096, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under He-P 4030.03(h) or (i) or equivalent regulations of the Nuclear Regulatory Commission, an Agreement State, or a licensing state except in accordance with a specific license issued by the Nuclear Regulatory Commission pursuant to Section 32.18 of 10 CFR part 32, equivalent regulations of an agreement state or a licensing state.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99

He-P 4030.04 Exemptions, U.S. Government Contractors. Any U.S. Nuclear Regulatory Commission and U.S. Department of Energy Contractor or subcontractor of the following categories operating within this state shall be exempt from this part to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers, owns, or acquires sources of radiation:

(a) Prime contractors performing work for the NRC or DOE at U.S. Government-owned or controlled sites;

(b) Prime contractors performing research in, or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof;

(c) Prime contractors using or operating nuclear reactors or other nuclear devices in a U.S. Government-owned vehicle or vessel; and

(d) Any other prime contractor or subcontractor when the state and the NRC jointly determine that:

(1) Under the terms of the contract or subcontract, there is assurance that the work thereunder can be accomplished without undue risk to the public health and safety; and

(2) The exemption of such contractor or subcontractor is otherwise appropriate.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99

He-P 4030.05 Radioactive Drug: Capsules Containing Carbon-14 Urea for "In Vivo" Diagnostic Use for Humans.

(a) Except as provided in He-P 4030.05(b) and (c), any person is exempt from the requirements for a license set forth in He-P 4030 and He-P 4035, provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing 37 kBq (1μ Ci) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

(b) Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to He-P 4035.

(c) Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive a specific license pursuant to He-P 4032.10.

(d) Nothing in this section relieves persons from complying with applicable FDA, Federal, and other State requirements governing receipt, administration, and use of drugs.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99

He-P 4030.06 Types of Licenses. Licenses for radioactive materials shall be of the following:

(a) General licenses as provided in He-P 4031 shall be without the filing of an application with the DHHS/BRH or the issuance of licensing documents to the particular persons.

(b) Specific licenses which require the submission of an application to the DHHS/BRH and the issuance of a licensing document by the DHHS/BRH.

(c) Specific license by rule which is issued without the necessity of filing an application for a specific license in the following circumstances:

(1) When a site must be timely remediated of contamination by radioactive materials that are subject to licensing under these rules but are unlicensed;

(2) When radioactive materials existing as a result of improper handling, spillage, accidental contamination, or unregulated or illegal possession, transfer, or receipt, must be stored and those materials have not been licensed under these rules.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99

He-P 4030.07 Specific Licenses, Filing or Application. Application for specific licenses shall be filed in compliance with the following provisions:

(a) Applications for specific licenses shall be filed on a form prescribed by the DHHS/BRH in He-P 4004.

(b) The DHHS/BRH may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the DHHS/BRH to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(c) Each application shall be signed by the applicant or licensee or a person duly authorized by the applicant or the licensee to act for and on his behalf.

(d) An application for a license may include a request for a license authorizing one or more activities.

(e) In the application, the applicant may incorporate by reference, information contained in previous applications, statements, or reports filed with the DHHS/BRH, provided such references are clear and specific.

(f) Applications and documents submitted to the DHHS/BRH may be made available for public inspection except that the DHHS/BRH shall withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

(g) An application for a license to receive and possess radioactive material for commercial waste disposal by land burial or for the conduct of any other activity which the DHHS/BRH determines will affect the quality of the environment shall be filed at least 9 months prior to commencement of construction of the plant or facility in which the activity will be conducted and shall be accompanied by an environmental report.

(h) Each application for a radioactive material license, other than a license exempted from He-P 4070 of this chapter, or an application for amendment of a license shall be accompanied by the fee prescribed in He-P 4070.

(i) An application for a specific license to authorize receipt, possession or use of radioactive material in the form of a sealed source or in a device that contains a sealed source shall either:

(1) Identify the sealed source or device that contains a sealed source by manufacturer and model number as filed in an evaluation sheet in the U.S. Department of Health and Human Services "Radioactive Material Reference Manual" or in the U.S. Nuclear Regulatory Commission "Registry of Radioactive Sealed Sources and Devices"; or

(2) Contain the information identified in He-P 4032.12.

(j) As provided by He-P 4030.09(f), certain applications for specific licenses filed under He-P 4030, must contain a proposed decommissioning funding plan or a certification of financial assurance for decommissioning.

(k) For applications to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in He-P 4030.08, TABLE 4030.1, the following requirements pertain:

(1) Each application shall contain either:

a. An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or

b. An emergency plan for responding to a release of radioactive material.

(2) The DHHS/BRH may use one or more of the following factors to support an evaluation submitted under He-P 4030.07(k)(1)a.:

a. The radioactive material is physically separated so that only a portion could be involved in an accident;

b. All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

c. The release fraction in the respirable size range would be lower than the release fraction shown in TABLE 4030.1 due to the chemical or physical form of the material;

d. The solubility of the radioactive material would reduce the dose received;

e. Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in TABLE 4030.1;

f. Operating restrictions or procedures would prevent a release fraction as large as that shown in TABLE 4030.1; or

g. Other factors appropriate for the specific facility.

(3) An emergency plan for responding to a release of radioactive material submitted under He-P 4030.06(k)(1)b. shall include the following information:

a. A brief description of the licensee's facility and area near the site.

b. An identification of each type of radioactive material accident for which protective actions may be needed.

c. A classification system for classifying accidents as alerts or site area emergencies.

d. Identification of the means of detecting each type of accident in a timely manner.

e. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

f. A brief description of the methods and equipment to assess releases of radioactive materials.

g. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the DHHS/BRH; also responsibilities for developing, maintaining, and updating the plan.

h. A commitment to and brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers.

i. A control point shall be established.

j. The notification and coordination shall be planned so unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination.

k. The licensee shall also commit to notify the DHHS/BRH immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

l. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to offsite response organizations and to the DHHS/BRH.

m. A brief description of the frequency, performance objectives and plans for the training

that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall:

1. Familiarize personnel with site-specific emergency procedures.

2. Thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

n. A brief description of the means of restoring the facility to a safe condition after an accident.

o. Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies.

p. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

(4) The exercises required by He-P 4030.06(k)(3)o. shall provide for:

a. Quarterly communications checks with offsite response organizations which shall include the check and update of all necessary telephone numbers.

b. The invitation to offsite response organizations to participate in the biennial exercises.

c. Accident scenarios postulated as most probable for the specific site and which scenarios shall not be known to most exercise participants.

d. Critiques of each exercise using individuals not having direct implementation responsibility for the plan and which shall evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response and which shall be corrected.

(5) The licensee shall allow the offsite response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to DHHS/BRH.

(6) The licensee shall provide any comments received within the 60 days to the DHHS/BRH with the emergency plan.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99

He-P 4030.08 Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release. These quantities shall be as set forth in TABLE 4030.1 below:

TABLE 4030.1 Quantities of Radioactive Materials Requiring
Consideration of the Need for an Emergency Plan for Responding to a Release

Radioactive Material	**Release fraction**	**Quantity (curies)**
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9 (20 mg)
Carbon-14	.01	50,000
	.01(non-carbon dioxide)	
Cerium-141	.01	10,000
Cerium- 144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Germanium-68	.01	2,000
Gadolinium-153	.01	5,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114m	.01	1,000
Indium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8

Manganese-58	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorous-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.0	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid non-combustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma[1]	.001	10,000
Any other alpha emitter	.001	2

Contaminated equipment alpha	.0001	20
Packaged waste, alpha[1]	.0001	20
Combinations of radioactive materials listed above[2]		

[1]Waste packaged in Type B containers does not require an emergency plan.

[2]For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Schedule C exceeds one.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99

He-P 4030.09 Specific Licenses, Requirements for Issuance. A license application shall be approved if the DHHS/BRH determines that:

(a) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these rules in such a manner as to minimize danger to public health and safety or property; and

(b) The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property; and

(c) The issuance of the license will not be inimical to the health and safety of the public; and

(d) The applicant satisfies any applicable special requirements in He-P 4031 through He-P 4035 and He-P 4039; and

(e) In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, the applicant satisfies any applicable special requirements in He-P 4060 through He-P 4064.

(f) In the case of an application for a license to receive and possess radioactive material for the conduct of any activity which the DHHS/BRH determines will significantly affect the quality of the environment, a license application for the facility in which the activity will be conducted shall be reviewed and approved by the DHHS/BRH before any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site other than site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

(g) Issuance of a license authorizing the activities of He-P 4030.09(f) shall be based upon a consideration by the DHHS/BRH of the environmental, economic, technical and other benefits in comparison with the environmental costs available alternatives and a determination that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values.

(h) Violation of He-P 4030.09(f) prior to review and approval by the DHHS/BRH shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility.

(i) Each applicant for a specific license authorizing the possession and use of special nuclear material, source material, or radioactive material in quantities and amounts in excess of those indicated in Table 4030.2 below shall submit a decommissioning funding plan.

TABLE 4030.2 Quantities And Amounts Requiring Decommissioning Funding Plan

Type of Material	Exceeding
Special Nuclear Material	10^5 times He-P 4091
Source Material	100 mCi in readily dispersible form
Radioactive Material (Unsealed)	Half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in He-P 4091

(j) The decommissioning funding plan shall be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1, where R is the sum of the ratios of quantity of each isotope to the applicable value in He-P 4091.

(k) Each applicant for or holder of a specific license authorizing possession and use of special nuclear material, source material, or radioactive material in excess of the values indicated in Table 4030.3 shall:

(1) Submit to DHHS/BRH a decommissioning funding plan as described in He-P 4030.09(m); or

(2) Submit to DHHS/BRH a certification that financial assurance for decommissioning shall be provided in the amount prescribed by Table 4030.3 below using one of the methods described in He-P 4030.09(n); and

(3) Submit to DHHS/BRH as a part of the certification, a copy of the financial instrument obtained to satisfy the requirement of He-P 4030.09(n).

TABLE 4030.3 Financial Assurance Amounts For Decommissioning

Type of Radioactive Material	Exceeding	Assurance Amount
Special Nuclear	Greater than 10^4 but less than or equal to 10^5 times the applicable quantities as indicated in He-P 4091. For a combination of isotopes, if R, as defined in He-P 4030.09(j) divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.	$750,000
	Greater than 10^3 but less than or equal to 10^4 times the	$150,000

Type of Radioactive Material	Exceeding	Assurance Amount
	applicable quantities as indicated in He-P 4091. For a combination of isotopes, if R, as defined in He-P 4030.09(j) divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.	
Source Material	Greater than 10 mCi but less than or equal to 100 mCi in a readily dispersible form. For a combination of isotopes, if R, as defined in He-P 4030.09(j) divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1.	$150,000
Radioactive Material	Half life greater than 120 days and in quantities:	
Radioactive Material	Greater than 10^4 but less than or equal to 10^5 times applicable quantities in unsealed form as indicated in He-P 4091. For a combination of isotopes, if R, as defined in He-P 4030.09(j) divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.	$750,000
	Greater than 10^3 but less than or equal to 10^4 times the applicable quantities in unsealed form as indicated in He-P 4091. For a combination of isotopes, or if R, as defined in He-P 4030.09(j) divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1.	$150,000
	Greater than 10^{10} times the applicable quantities in sealed sources or plated sources. For a combination of isotopes, if R, as defined in He-P 4030.09(j) divided by 10^{10} is greater than 1.	$75,000

(l) Certification may state that the appropriate assurance shall be obtained after the application has been approved and the license issued but prior to the receipt of licensed material.

(m) Each decommissioning funding plan shall contain a cost estimate for decommissioning, and a description of the method of assuring funds for such including means of adjusting cost estimates and associated funding levels over the life of the facility.

(n) Financial assurance for decommissioning shall be provided by any one or more of the following methods:

(1) Prepayment; and

(2) A surety method or insurance; and

(3) An external sinking fund; and

(4) Any other funding methods which shall be demonstrated by the applicant or licensee to

provide comparable assurance to methods listed in He-P 4030.09(k)(1) through (3); and

(5) In the case of state, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on Table 4030.3, and indicating that funds for decommissioning shall be obtained when necessary.

(o) The prepayment method shall be:

(1) In the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities; and

(2) Deposited prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets that will retain their value over the projected operating life of the facility; and

(3) In an amount such that the principal plus accumulated earnings shall be sufficient to pay the necessary costs.

(p) The surety method or insurance shall be in the form of a surety bond, letter of credit, line of credit, secured interest or other guarantee method such that the costs shall be paid should the licensee default.

(q) Any surety or insurance under He-P 4030.09(l) shall contain the following conditions:

(1) The surety of insurance shall be open-ended or, if written for a specified term, such as 5 years, shall be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the DHHS/BRH, the trust account, and the licensee of its intention not to renew.

(2) The surety or insurance shall provide that the beneficiary may automatically collect prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the DHHS/BRH within 30 days after receipt of notification of cancellation.

(3) The beneficiary of the surety or insurance shall be a trust account and trustee such as a state or federal government agency or entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

(4) The surety or insurance shall remain in effect until the DHHS/BRH has terminated the license.

(r) An external sinking fund shall be:

(1) In the form of a trust, escrow account, government fund, certificate of deposit or deposit of government securities; and

(2) Established and maintained by the periodic deposit of a prescribed amount into an account segregated from licensee assets and outside the licensee's administrative control; and

(3) In a total amount for which the periodic deposits plus accumulated earnings shall be sufficient to pay the necessary costs at the time termination of operation is expected; and

(4) Deposited to at least annually; and

(5) Coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking fund.

(s) Each person licensed under He-P 4030 shall keep records of information important to the safe and effective decommissioning of the facility in a specific location reserved for this purpose until the license is terminated by the DHHS/BRH.

(t) If records of relevant information are kept for other purposes, reference to these records and their locations shall be kept with the records for decommissioning.

(u) Records important to decommissioning shall consist of:

(1) Recordings of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site which may be limited to instances:

a. When contamination remains after any cleanup procedures; or

b. When there is reasonable likelihood that contaminants may have spread to inaccessible areas such as seepage into porous materials such as concrete.

(2) Information on identification of involved nuclides, including quantities, forms, and concentrations if known.

(3) As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used or stored, and of locations of possible inaccessible contamination such as buried pipes; but if drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

(4) Recordings of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and recordings of the funding method used for assuring funds if either a funding plan or certification is used.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99

He-P 4030.10 Specific Licenses, Issuance. Upon a determination that an application meets the requirements of the act and the rules of the DHHS/BRH, the DHHS/BRH shall issue a specific license authorizing the proposed activity.

(a) The DHHS/BRH shall incorporate in any license at the time of issuance or thereafter, by appropriate rule, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material subject to this part as it deems appropriate or necessary in order to:

(1) Minimize danger to public health and safety or property; and

(2) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

(3) Prevent loss or theft of material subject to this part.

(b) Specific licenses shall be issued to named persons upon applications filed pursuant to He-P 4030 and He-P 4004.

(c) Each license issued pursuant to this part shall be subject to all the provisions of the act and to all rules of the DHHS/BRH.

(d) Neither the license nor any right under the license shall be assigned or otherwise transferred in violation of the provision of the act.

(e) Each person licensed by the DHHS/BRH pursuant to this part shall confine his use and possession of the material licensed to conditions specified on the license, such as:

(1) Standard licensing conditions as set forth in these Rules, or

(2) Conditions formulated specifically for an individual license.

(f) Each licensee shall notify the DHHS/BRH in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

(g) Each licensee shall notify the DHHS/BRH in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 of the United States Code by or against:

(1) The licensee; or

(2) An entity as that term is defined in 11 U.S.C. 101(14) controlling the licensee or listing the license or licensee as property of the estate; or

(3) An affiliate as that term is defined in 11 U.S.C. 101(2) of the licensee.

(h) The notification specified in He-P 4030.10(f) shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99

He-P 4030.11 Specific Licenses, Expiration.

(a) Except as provided in He-P 4030.12, each specific license shall expire at the end of one year.

(b) Each licensee shall notify the DHHS/BRH, in writing, and request termination of the license when the licensee decides to terminate all activities involving radioactive material authorized under the license. This notification and request for termination of the license shall include the reports and information specified in He-P 4030.11(d)(4) and (5).

(c) No less than 30 days before the expiration date specified in the license, the licensee shall either:

(1) Submit an application for license renewal under He-P 4030.12; or

(2) Notify the DHHS/BRH, in writing, if the licensee decides not to renew the license.

(d) If a licensee does not submit an application for license renewal under He-P 4030.11, the licensee shall, on or before the expiration date specified in the license:

(1) Terminate use of radioactive material; and

(2) Remove radioactive contamination in accordance with He-P 4023; and

(3) Dispose of radioactive material in accordance with He-P 4023; and

(4) Submit a completed DHHS/BRH Form BRH-10; and

(5) Submit a radiation survey report of the licensed permanent location(s) of use and storage to confirm that the removable and fixed contamination levels are in accordance with levels specified in He-P 4021.21.

a. Report levels of radiation in units of microrads per hour of beta and gamma radiation at 1 centimeter and gamma radiation at 1 meter from surfaces and report levels of radioactivity, including alpha, in:

1. Units of transformations per minute per 100 square centimeters or microcuries per 100 square centimeters removable and fixed on surfaces; and

2. Microcuries per milliliter in water; and

3. Picocuries per gram in contaminated solids such as soils or concrete.

b. Specify the survey or measurement instrument(s) used for conducting the survey and certify that each instrument was properly calibrated and tested.

(e) If no residual radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination of the location(s) was found.

(f) If detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, the license shall continue to be in effect beyond the expiration date, with respect to possession of residual radioactive material present as contamination until such time as the DHHS/BRH notifies the licensee in writing that the license is terminated. During this time the licensee shall be subject to the provisions of He-P 4030.11(h).

(g) If detectable levels of residual radioactive contamination attributable to activities conducted under the license are found, the licensee shall submit a plan for decontamination of the residual radioactive contamination which shall include in addition to the information submitted under He-P 4030.11(d)(4) and (5), any expected levels of residual radioactive contamination which will remain at the time the license is terminated.

(h) Each licensee who possesses residual radioactive material under He-P 4030.11(d)(3), following the expiration date specified in the license shall:

(1) Limit actions involving radioactive material to those related to decontamination and other activities related to preparation for release for unrestricted use; and

(2) Continue to control entry to restricted areas until they have met the provisions of He-P 4020 for release for unrestricted use and the DHHS/BRH has notified the licensee in writing that the license is terminated.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99

He-P 4030.12 Specific Licenses, Renewal.

(a) Applications for renewal of specific licenses shall be filed in accordance with He-P 4030.07.

(b) In any case in which a licensee, not less than 30 days prior to expiration of his existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until the application has been finally determined by the DHHS/BRH.

(c) If a licensee does not submit an application for license renewal, the licensee shall comply with the provisions of He-P 4030.10.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99

He-P 4030.13 Specific Licenses, Amendment at Request of Licensee. Applications for amendment of a license shall:

(1) Be filed in accordance with He-P 4030.07; and

(2) Specify the respects in which the licensee desires his license to be amended and the grounds for such amendment.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99

He-P 4030.14 Specific Licenses, DHHS/BRH Action of Applications to Renew or Amend. In considering an application by a licensee to renew or amend his license, the DHHS/BRH shall apply the criteria set forth in this chapter for granting of an initial license.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99

He-P 4030.15 Specific Licenses, Inalienability. No license issued or granted under this part and no right to possess or utilize radioactive material granted by any license issued pursuant to this part shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the DHHS/BRH, after securing full information, find that the transfer is in accordance with the provisions of the act, and gives its consent in writing.

Source. (See Revision Note at part heading for He-P 4030)

#6942, eff 2-1-99

He-P 4030.16 Specific Licenses, Transfer of Material.

(a) No licensee shall transfer radioactive material except as authorized pursuant to Part He-P 4030.

(b) Except as otherwise provided in his license and subject to the provisions of He-P 4030.16(c) and (d), any licensee may transfer radioactive material:

(1) To the DHHS/BRH only after receiving prior approval from the DHHS/BRH; or

(2) To the U.S. Nuclear Regulatory Commission; or

(3) To any person exempt from He-P 4000 to the extent permitted under such exemption; or

(4) To any person authorized to receive such material under terms of a general license or its equivalent or a specific license or equivalent licensing document, issued by the DHHS/BRH, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State, or to any person otherwise authorized to receive such material by the Federal government of any agency thereof, the DHHS/BRH, an Agreement State, or a Licensing State; or

(5) As otherwise authorized by the DHHS/BRH in writing.

(c) Before transferring radioactive material to a specific licensee of the DHHS/BRH, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State prior to receipt of the radioactive material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

(d) The following methods for the verification required by He-P 4030.16(c) shall be acceptable:

(1) The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate; or

(2) The transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; or

(3) For emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within 10 days; or

(4) Transferor may obtain other sources of information compiled by a reporting service from official records of the DHHS/BRH, the U.S. Nuclear Regulatory Commission, or the licensing agency of an Agreement State or a Licensing State as to the identity of licensees and the scope and expiration dates of licenses and registration; or

(5) When none of the methods of verification described in He-P 4030.16(d)(1) to (4) are readily

available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the DHHS/BRH, the U.S. Nuclear Regulatory Commission, or the licensing agency of an Agreement State or a Licensing State that the transferee is licensed to receive the radioactive material.

(e) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of He-P 4037.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99

He-P 4030.17 Specific Licenses, Modification, Revocation, and Termination.

(a) The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the act, or by reason of rules, and orders issued by the DHHS/BRH.

(b) Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the act, or because of conditions revealed by such application or statement of fact or any report, record or inspection or other means which would warrant the DHHS/BRH to refuse to grant a license on an original application, or for violation of, the terms and conditions of the act, or the license, or of any rule, regulation, or order of the DHHS/BRH.

(c) Except in cases of willfulness or those in which the public health, interest, or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

(d) The DHHS/BRH shall terminate a specific license upon request submitted by the licensee to the DHHS/BRH in writing, provided that the licensee shall meet the requirements of He-P 4030.16.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99

He-P 4030.18 Specific Licenses, Reciprocal Recognition.

(a) Subject to He-P 4000, any person who holds a specific license or equivalent licensing document from the Nuclear Regulatory Commission, an Agreement State, or a Licensing State and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this state for a period not in excess of 180 days in any calendar year, provided that:

(1) The licensing document does not limit the activity authorized by such document to specified installations or locations; and

(2) The out-of-state licensee notifies the DHHS/BRH in writing at least 3 days prior to engaging in such activity.

(3) Such notification shall indicate the location, period, and type of proposed possession and use within this state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3-day period would impose an undue hardship on the out-of-state licensee, he may, upon application to the DHHS/BRH, obtain permission to proceed sooner; and

(4) The out-of-state licensee complies with all applicable rules of the DHHS/BRH and with all the terms and conditions of his licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the DHHS/BRH.

(5) The out-of-state licensee supplies such other information as the DHHS/BRH may request; and

(6) The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this section except by transfer to a person:

a. Specifically licensed by the DHHS/BRH or by the U.S. Nuclear Regulatory Commission to receive such material; or

b. Exempt from the requirements for a license for such material under He-P 4030.03.

(b) Notwithstanding the provisions of He-P 4030.18(a), any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State authorizing the holder to manufacture, install, or service a device check described in He-P 4031.02(c) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install and service such device in this state provided that:

(1) Such person shall file a report with the DHHS/BRH within 30 days after the end of each calendar quarter in which any device is transferred to or serviced in this state. Each such report shall identify each general licensee by:

a. Name and address; and

b. The type of device transferred; and

c. The quantity and type of radioactive material contained in the device.

(2) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license, or equivalent licensing document, issued to such person by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State; and

(3) Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited;" and

(4) The holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in He-P 4031.02.

(c) The DHHS/BRH may withdraw, limit, or qualify its acceptance of any specific license or

equivalent licensing document issued by another agency, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

Source. (See Revision Note at part heading for He-P 4030) #6942, eff 2-1-99

PART He-P 4031 GENERAL LICENSES

REVISION NOTE:

Doc. #6942, effective 2-1-99, repealed Parts He-P 2030, 2031, 2032, 2033, 2034, 2035, 2042 and 2093 relative to Radiation and Radioactive Material and adopted new rules to replace them and renumbered them as He-P 4030, 4031, 4032, 4033, 4034, 4035, 4093 and 4096.

He-P 4031.01 General Licenses - Source Material.

(a) A general license shall be issued authorizing use and transfer of not more than 15 pounds of source material at any one time by commercial and industrial firms, research, educational, medical institutions, state or local government agencies for research, development, educational, commercial, or operational purposes; provided no person pursuant to this general license receives more than a total of 150 pounds of source material in any one calendar year.

(b) Persons who receive, possess, use, or transfer source material pursuant to the general license issued in He-P 4031.01(a) shall be exempt from the provisions of He-P 4019 through He-P 4023 provided that such person is not also in possession of source material under a specific license issued pursuant to He-P 4030.

(c) Persons who receive, possess, use or transfer source material pursuant to the general license in He-P 4031.01(a) are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as authorized by the DHHS/BRH in a specific license.

(d) A general license shall be issued authorizing the receipt of title to source material without regard to quantity, but shall not authorize the person to receive, possess, use, or transfer the source material.

(e) A general license shall be issued to receive, acquire, possess, use, or transfer depleted uranium provided that:

(1) The depleted uranium is contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device in accordance with the provisions of He-P 4031(e)(2), (3), and (4).

(2) The depleted uranium authorized in He-P 4031.01(e)(1) is contained only in industrial products or devices which have been manufactured in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

(3) A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by He-P 4031.01(e)(1):

a. Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except when a treatment or process is for repair or restoration of the plating or covering of the depleted uranium.

b. Shall not abandon such depleted uranium.

c. Shall transfer or dispose of depleted uranium only by transfer in accordance with the provisions of He-P 4030.15.

d. When depleted uranium is transferred in accordance with He-P 4031.01(e)(3)c, the transferor shall furnish the transferee a copy of this rule.

e. In the case where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission's, an Agreement State's, or a Licensing State's regulation equivalent to He-P 4031.01(e)(1), the transferor shall furnish the transferee a copy of He-P 4031 accompanied by a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

f. Within 30 days of any transfer, the transferor shall report in writing to the DHHS/BRH the name and address of the person receiving the depleted uranium pursuant to such transfer.

g. A general licensee shall not export depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

(4) Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by He-P 4031.01(e) shall be exempt from the requirements of He-P 4019 through He-P 4023 with respect to the provisions of He-P 4031.

Source. (See Revision Note at part heading for He-P 4031) #6942, eff 2-1-99

He P 4031.02 General Licenses - Radioactive Material Other Than Source Material.

(a) A general license is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated into the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission for use pursuant to 10 CFR 31, Section 31.3.

(b) The general license provided in He-P 4031.02(a) shall be subject to the provisions of He-P 4001 through He-P 4003, He-P 4019 through He-P 4023, He-P 4030.03, He-P 4030.10, He-P 4030.16, He-P 4030.17 and He-P 4037.

(1) Devices designed for use as static eliminators which shall contain, as a sealed source or sources, radioactive material consisting of not more than 500 microcuries of polonium 210 per device.

(2) Devices designed for ionization of air which shall contain, as a sealed source or sources, radioactive material consisting of not more than 500 microcuries of polonium 210 or 50 millicuries of hydrogen 3 (tritium) per device.

(c) A general license is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of
He-P 4031.02(d), (e), and (f), radioactive material, excluding special nuclear material, contained in devices

designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(d) The general license in He-P 4031.02(c) shall apply only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific license issued by the DHHS/BRH pursuant to He-P 4032 or in accordance with the specifications contained in a specific license issued by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State which authorizes distribution of devices to persons generally licensed by the NRC, an Agreement State or a Licensing State.

(e) Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in He-P 4031.02(c) shall:

(1) Assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, shall be maintained thereon and shall comply with all instructions and precautions provided by such labels;

(2) Assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than six-month intervals or at such other intervals as are specified on the label; however,

a. Devices containing only krypton shall not be required to be tested for leakage of radioactive material; and

b. Devices containing only tritium or not more than 100 microcuries of other beta and/or gamma emitting material or 10 microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation shall not be required to be tested for any purpose.

(3) Assure that the tests required by He-P 4031.02(e)(2) and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

a. In accordance with the instructions provided by the labels; or

b. By a person holding a specific license from the DHHS/BRH, the NRC, an Agreement State, or a Licensing State to perform such activities;

(4) Maintain records showing compliance with the requirements He-P 4031.02(e)(2) and (3) which:

a. Show the results of tests; and

b. Show the dates of performance of, and the names of persons performing, testing, installation servicing, and removal from installation concerning the radioactive material, its shielding or containment.

(5) Shall retain records as follows:

a. Each record of a test for leakage or radioactive material required by He-P 4031.02(e)(2) shall be retained for three years after the next required leak test is performed or until the sealed source is transferred or disposed of.

b. Each record of a test on the on-off mechanism and indicator required by He-P 4031.02(e)(2) shall be retained for three years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of.

c. Each record that is required by He-P 4031.02(e)(3) shall be retained for three years from the date of the recorded event or until the device is transferred or disposed of.

(6) Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding a specific license from the DHHS/BRH, the NRC, an Agreement State, or a Licensing State to repair such devices, or disposed of by transfer to a person authorized by a specific license to receive the radioactive material contained in the device and, within 30 days, furnish to the DHHS/BRH a report containing a brief description of the event and the remedial action taken;

(7) Not abandon the device containing radioactive material;

(8) Except as provided in He-P 4031.02(e)(9) transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the DHHS/BRH, the NRC, an Agreement State, or a Licensing State whose specific license authorizes him to receive the device and within 30 days after transfer of a device to a specific licensee shall furnish to the DHHS/BRH a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device, except that no report shall be required if the device is transferred to the specific licensee in order to obtain a replacement device;

(9) Shall transfer the device to another general licensee only:

a. Where the device remains in use at a particular location, in which case the transferor shall give the transferee a copy of this rule and any safety documents identified in the label on the device and, within 30 days of the transfer, report to the DHHS/BRH the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and/or position of an individual who may constitute a point of contact between the DHHS/BRH and the transferee; or

b. Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee.

(10) Shall comply with the provisions of He-P 4021.12 and 4021.13 for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of He-P 4019 through He-P 4023.

(f) The general license in He-P 4031.02(c) shall not authorize the manufacture or import of devices containing radioactive material.

(g) The general license provided in He-P 4031.02(c) shall be subject to the provisions of He-P 4001 through He-P 4003, He-P 4030.10, He-P 4030.16, He-P 4030.17, and He-P 4037.

(h) A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium 147 contained in luminous safety devices for use in aircraft, provided:

(1) Each device contains not more than 10 curies of tritium or 300 millicuries of promethium 147; and

(2) Each device has been manufactured, assembled or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured or assembled in accordance with the specifications contained in a specific license issued by the DHHS/BRH, an Agreement State, or a Licensing State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in section 32.53 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission.

(i) Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in He-P 4031.02(h) shall be exempt from the requirements of He-P 4019 through 4023, except that they shall comply with the provisions of sections He-P 4021.12 and He-P 4021.13.

(j) The general license in He-P 4031.02(h) shall not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium 147.

(k) This general license in He-P 4031.02(h) shall not authorize the ownership, receipt, acquisition, possession or use of promethium 147 contained in instrument dials.

(l) The general license in He-P 4031.02(h) shall be subject to the provisions of He-P 4001 through He-P 4003, He-P 4030.10, He-P 4030.16, He-P 4030.17 and He-P 4037.

(m) A general license shall be issued to those persons listed below to own, receive, acquire, possess, use, and transfer in accordance with the provisions of He-P 4031.02(p), (q) and (s) americium 241 in the form of calibration or reference sources:

(1) Any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive materials; and

(2) Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes him to receive, possess, use, and transfer special nuclear material.

(n) A general license shall be issued to receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of
He-P 4031.02(p), (q), and (s) to any person who holds a specific license issued by the DHHS/BRH which authorizes him to receive, possess, use, and transfer radioactive material.

(o) A general license shall be issued to any person to own, receive, possess, use, and transfer radium in the form of calibration or reference sources in accordance with equivalent provisions of He-P 4031.02(p), (q), and (s) who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material.

(p) The general licenses in He-P 4031.02(m)(n) and (o) shall apply only to calibration or reference

sources which have been manufactured in accordance with the specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission, pursuant to section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific license or equivalent licensing document issued to the manufacturer by the DHHS/BRH, an Agreement State, or a Licensing State pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or section 70.39 of 10 CFR Part 70 of the regulations of the U.S. Nuclear Regulatory Commission.

(q) The general licenses provided in He-P 4031.02(m)(n) and (o) shall be subject to the provisions of He-P 4001 through He-P 4003, He-P 4019 through He-P 4023, He-P 4030.10, He-P 4030.16, He-P 4030.17 and He-P 4037.

(r) Persons who own, receive, acquire, possess, use and transfer one or more calibration or reference sources pursuant to He-P 4031.02(m), (n), or (o):

(1) Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries of americium 241 and 5 microcuries of plutonium in such sources; and

(2) Shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements or a substantially similar statement which contains the information called for in the following statement:

a. "The receipt, possession, use and transfer of this source, Model_____, Serial No._____, are subject to a general license and the regulations of the Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label."

CAUTION-RADIOACTIVE MATERIAL
THIS SOURCE CONTAINS (AMERICIUM 241) OR (PLUTONIUM) or other named material
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE

(Name of Manufacturer or Importer;)

b. The receipt, possession, use and transfer of this source, Model_____, Serial No. _____, are subject to a general license and the regulations of a Licensing State. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL
THIS SOURCE CONTAINS RADIUM-226
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE

(Name of Manufacturer or Importer;)

(3) Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the DHHS/BRH, the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State to receive the source; and

(4) Shall store such source, except when the source is being used, in a closed container designed

and constructed to contain americium 241, plutonium or radium-226 which might otherwise escape during storage; and

(5) Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

(s) The general licenses in He-P 4031.02(m), (n), and (o) shall not authorize the manufacture of calibration or reference sources containing americium-241, plutonium, or radium-226.

(t) A general license shall be issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this part, this general license does not authorize the manufacture, production, transfer, receipt, possession, or use of radioactive material.

(u) A general license shall be issued to own, receive, acquire, possess, use and transfer strontium 90 contained in ice detection devices, provided each device contains not more than fifty microcuries of strontium 90 and each device has been manufactured or imported in accordance with a specific license issued by the Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license or equivalent licensing document issued by the DHHS/BRH, an Agreement State, or a Licensing State to the manufacturer of such device pursuant to licensing requirements equivalent to those in section 32.61 of 10 CFR Part 32 of the regulations of the Nuclear Regulatory Commission.

(v) Persons who own, receive, acquire, possess, use, or transfer strontium 90 contained in ice detection devices pursuant to the general license in He-P 4031.02(u) shall:

(1) Upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating, to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific license or equivalent licensing document from the Nuclear Regulatory Commission, an Agreement State, or a Licensing State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of those rules; and

(2) Assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

(3) Be exempt from the requirements of He-P 4019 through He-P 4023, except that such person shall comply with the provisions of He-P 4023, He-P 4021.12 and He-P 4021.13.

(w) The general license in He-P 4031.02(u) shall not authorize the manufacture, assembly, disassembly or repair of strontium 90 in ice detection devices.

(x) The general license in He-P 4031.02(u) shall be subject to the provisions of He-P 4001 through He-P 4003, He-P 4030.10, He-P 4030.16, He-P 4030.17, and He-P 4037.

Source. (See Revision Note at part heading for He-P 4031) #6942, eff 2-1-99

He-P 4031.03 General License to Install Devices Generally Licensed in He-P 4031.02. Any person holds a specific license issued by an Agreement State, the Nuclear Regulatory Commission or Licensing State, authorizing the holder to manufacture, install, or service a device described in He-P 4031.02 within such Agreement State, non-Agreement State or Licensing State, is hereby granted a general license to install

and service such device in this state and a general license to install and service such device in offshore waters, as defined in 10 CFR provided:

(a) The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the Agreement State, the Nuclear Regulatory Commission or Licensing State.

(b) Such person assures that any labels required to be affixed to the device under regulations of the Agreement State, the Nuclear Regulatory Commission or Licensing State, which licensed manufacture of the device bear a statement that removal of the label is prohibited.

Source. (See Revision Note at part heading for He-P 4031) #6942, eff 2-1-99

PART He-P 4032 SPECIFIC LICENSES FOR MANUFACTURE OR TRANSFER OF CERTAIN ITEMS CONTAINING RADIOACTIVE MATERIAL

REVISION NOTE:

Doc. #6942, effective 2-1-99, repealed Parts He-P 2030, 2031, 2032, 2033, 2034, 2035, 2042 and 2093 relative to Radiation and Radioactive Material and adopted new rules to replace them and renumbered them as He-P 4030, 4031, 4032, 4033, 4034, 4035, 4093 and 4096.

He-P 4032.01 Purpose.

(a) This part shall prescribe requirements for the issuance of specific licenses to persons who manufacture or initially transfer items containing byproduct material for sale or distribution to:

(1) Persons exempted from the licensing requirements of He-P 4030;

(2) Persons generally licensed under He-P 4031 or He-P 4035.

(b) This part shall prescribe requirement for manufacturers or initial transferors of sealed source or devices containing sealed sources which are to be used by persons specifically licensed under He-P 4030 or equivalent regulations of an Agreement State or Licensing State.

Source. (See Revision Note at part heading for He-P 4032) #6942, eff 2-1-99

He-P 4032.02 Scope. The provisions and requirements of this part shall be in addition to, and not in substitution for, other requirements of this chapter.

Source. (See Revision Note at part heading for He-P 4032) #6942, eff 2-1-99

He-P 4032.03 Licensing the Manufacture and Distribution of Devices to Persons Generally Licensed.

(a) An application for a specific license to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally licensed under He-P 4031.02 or equivalent regulations of the U.S. NRC, an Agreement State or Licensing State shall be approved if:

(1) The applicant satisfies the general requirements of He-P 4030.09;

(2) The applicant submits complete information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions, and potential hazards of the device to provide assurance that:

a. The device can be safety operated by persons not having training in radiological protection;

b. Under ordinary conditions of handling, storage, and the use of the device, the radioactive material contained in the device shall:

1. Not be released or inadvertently removed from the device, and

2. It is unlikely that any person will receive a dose in excess of the limits specified in He-P 4020.06; and

c. Under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the organ doses in Table 4032.1 below:

Table 4032.1 Organ Doses Under Accident Conditions

Body Part	Organ Dose
Whole body; head and trunk; active blood-forming organs; gonads, or lens of eye	15 rems (150 mSv)
Hands and forearms; feet and localized areas of skin averaged over areas no longer than 1 square centimeter	200 rems (2 Sv)
Other organs	50 rems (500 mSv)

and;

(3) Each device bears a durable, legible, clearly visible label or labels, which contain in a clearly identified and separate statement:

a. Instructions and precautions necessary to assure safe installation, operation, and servicing of the device or identification of operating and service manuals used to provide this information;

b. The requirement, or exemption of requirement, for leak testing, or for testing any on-off mechanism and indicator, to include the maximum time interval for such testing, the identification of radioactive material by isotope, the quantity of radioactivity, and the date of determination of the quantity; and

c. The following statements:

1. The receipt, possession, use and transfer of this device Model_____ Serial No._____ are subject to a general license or the equivalent and the regulations of the U.S. NRC, the Agreement State or the Licensing State which has regulatory authority.

2. This label shall be maintained on the device in a legible condition.

3. Removal of this label is prohibited;

4. The words, "CAUTION - RADIOACTIVE MATERIAL" and

5. The name of the manufacturer or distributor.

(b) Should an applicant desire that a device be required to be leak tested or tested for proper operation

of the on-off mechanism and indicator, at intervals greater than 6 months, the DHHS/BRH shall consider at least the following information in determining the acceptable interval:

(1) Primary containment (source capsule);

(2) Protection of primary containment;

(3) Method of sealing containment;

(4) Containment construction materials;

(5) Form of contained radioactive material;

(6) Maximum temperature withstood during prototype test;

(7) Maximum pressure withstood during prototype tests;

(8) Maximum quantity of contained radioactive material;

(9) Radiotoxicity of contained radioactive material; and

(10) Operating experience with identical devices or similarly designed and constructed devices.

(c) In the event the applicant desires that the general licensee under He-P 4031, or under equivalent regulations of the NRC, an Agreement State, or a Licensing State be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator, or remove the device from installation the applicant shall include written instructions to be followed by the general licensee; the estimated calendar quarter doses associated with such activity or activities, and bases for such estimates, and

(d) Shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10% of the limits specified in He-P 4020.

(e) Each person licensed under He-P 4032 to distribute devices to generally licensed persons shall:

(1) Furnish a copy of the general license requirements contained in He-P 4031 to each person or intermediate person to whom the device is transferred prior to use pursuant to the general license.

(2) Furnish a copy of the general license contained in the NRC, Agreement State's, or Licensing State's regulation equivalent to He-P 4031, or furnish a copy of the general license contained in He-P 4031.02 to each person, or intermediate person to whom the device is transferred, accompanied by a note explaining that use of the device is regulated by the U.S. NRC, an Agreement State or Licensing State whose requirements substantially the same as those in He-P 4031.02.

(3) Report to the DHHS/BRH all transfers of such devices to persons for use under the general license in He-P. The report shall identify:

a. Each general licensee by name and address;

b. An individual by name and/or position who may constitute a point of contact between the DHHS/BRH and the general licensee;

c. The type and model number of device transferred;

d. The quantity and type of radioactive material contained in the device, and

e. One or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user.

(4) Report to the DHHS/BRH if no transfers have been made to persons generally licensed under He-P 4031.02 during the reporting period.

(5) The reports in He-P 4032.03(e)(3) and (4) shall cover each calendar quarter and shall be filed within 30 days thereafter.

(6) Report to the NRC all transfers of such devices to persons for use under the NRC general license in section 31.5 of 10 CFR Part 31.

(7) Report to the responsible Agreement State or Licensing State agency all transfers of such devices to persons for use under a general license in the Agreement State's or Licensing State's regulations equivalent to He-P 4031.

(8) Identify in the report the following:

a. Each general licensee by name and address;

b. An individual by name and/or position who may constitute a point of contact between the agency and the general licensee;

c. The type and model of the device transferred;

d. The quantity and type of radioactive material contained in the device; and

e. One or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user.

(9) Submit the reports required in He-P 4032.03(e)(6) and (7) within 30 days after the end of each calendar quarter in which such a device is transferred to the generally licensed person.

(10) Report to the NRC, if no transfers have been made to NRC licensees during the reporting period.

(11) Report to the Agreement State or Licensing State agency if no transfers have been made to that Agreement State or licensing State during the reporting period.

(12) Keep records showing:

a. The name;

b. Address;

c. The point of contact for each general licensee or intermediate person to whom transfers of radioactive material in devices for use pursuant to the general license provided in He-P 4031.02, or equivalent regulations of the NRC, an Agreement State or Licensing State have been made;

d. The date of each transfer;

e. The isotope;

f. The quantity of radioactivity in each device transferred;

g. The identity of any intermediate person; and

h. The requirements of He-P 4031 specifics for this transfer.

Source. (See Revision Note at part heading for He-P 4032) #6942, eff 2-1-99

He-P 4032.04 Licensing the Introduction of Radioactive Material Into Products in Exempt Concentrations.

(a) In addition to the requirements in He-P 4030.09, a specific license authorizing the introduction of radioactive material into a product or material owned by or in the possession of the licensee or another to be transferred to persons exempt under paragraph He-P 4030.03 shall be issued if:

(1) The applicant submits:

a. A description of the product or material into which the radioactive material will be introduced;

b. The intended use of the radioactive material and the product into which it is introduced;

c. The method of introduction;

d. The initial concentration of the radioactive material in the product or material;

e. The control methods to assure that no more than the specified concentration is introduced into the product or material;

f. The estimated time interval between introduction and transfer of the product or material; and

g. The estimated concentration of the radioactive material in the product or material at the time of transfer by the licensee; and

(2) The applicant provides reasonable assurance that:

a. The concentrations of radioactive material at the time of transfer will not exceed the concentration in He-P 4093;

b. That reconcentration of the radioactive material in concentrations exceeding those in He-P 4093 is not likely;

c. That use of lower concentrations is not feasible; and

d. That the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

(b) Each person licensed under He-P 4032.04 shall file an annual report with the DHHS/BRH.

(1) which shall identify:

a. The type and quantity of each product or material into which radioactive material has been introduced during the reporting period;

b. Name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction;

c. The type and quantity of radionuclide introduced into each such product or material; and

d. The initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the licensee.

(2) If no transfers of radioactive material have been made pursuant to He-P 4032.04 during the reporting period, the report shall so indicate.

(3) The report shall cover the year ending June 30.

(c) The report shall be filed within 30 days thereafter.

Source. (See Revision Note at part heading for He-P 4032) #6942, eff 2-1-99

He-P 4032.05 Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Group Licenses.

(a) An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to He-P 4035 shall be approved if:

(1) The applicant satisfies the requirements specified in He-P 4030.09;

(2) The applicant submits evidence that the applicant is at least one of the following:

a. Registered or licensed with the U.S. Food and Drug Administration (FDA) as a drug

manufacturer;

b. Registered or licensed with a state agency as a drug manufacturer;

c. Licensed as a pharmacy by a State Board of Pharmacy; or

d. Operating as a nuclear pharmacy within a medical institution.

(3) The applicant submits the following information:

a. The radionuclide;

b. The chemical and physical form;

c. The packaging including maximum activity per package; and

d. The shielding provided by the packaging of the radioactive material shall be appropriate for safe handling and storage of radiopharmaceuticals by group licensees; and

(4) The applicant satisfies the following labeling requirements:

a. A label is affixed to each transport radiation shield of a radioactive drug to be transferred for commercial distribution;

b. The label shall include:

1. The radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL";

2. The name of the radioactive drug or its abbreviation;

3. The quantity of radioactivity at a specified date and time; and

4. For radioactive drugs with a half life greater than 100 days, the time may be omitted.

c. A label affixed to each syringe, vial or other container used to hold a radioactive drug to be transferred for commercial distribution. The label required in He-P 4032.05 (a)(4) b. shall include:

1. The radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL"; and

2. An identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(5) The labels, leaflets or brochures required by He-P 4032.03(a)(4) shall be in addition to the labeling required by the Food and Drug Administration (FDA), and shall be separate from or, if approved by the FDA may be combined with the labeling required by FDA.

(b) A licensee described by He-P 4032.01(a)(2)c. or d.:

(1) May prepare radioactive drugs for medical use, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in He-P 4032.05(b)(2) and (b)(3), or an individual under the supervision of an authorized nuclear pharmacist, as specified in He-P 4035.

(2) May allow a pharmacist to work as an authorized pharmacist if:

a. This individual qualifies as an authorized nuclear pharmacist as defined in He-P 4035;

b. This individual meets the requirements specified in He-P 4035 and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

c. This individual is designated as an authorized nuclear pharmacist in accordance with He-P 4032.05(b)(3).

(3) The actions authorized in He-P 4032.05(b)(1) and (b)(2) are permitted in spite of more restrictive language in license conditions.

(4) May designate a pharmacist as defined in He-P 4003(cp) as an authorized nuclear pharmacist if the individual is identified as of December 2, 1994, as an "authorized user" on a nuclear pharmacy license issued by the DHHS/BRH under this part.

(5) Shall provide to the DHHS/BRH a copy of each individual's certification by the Board of Pharmaceutical Specialties, the Commission or Agreement State license or Licensing State license, or the permit issued by a licensee of broad scope, and a copy of the state pharmacy licensure or registration, no later than 30 days after the date that the licensee allows pursuant to He-P 4032.05(b)(2)a. and (b)(2)c., the individual to work as an authorized nuclear pharmacist.

(c) A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs as follows:

(1) The licensee shall have procedures for use of the instrumentation;

(2) The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-, emitting radioactive drugs prior to transfer for commercial distribution; and

(3) The licensee shall:

a. Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

b. Check each instrument for constancy and proper operation at the beginning of each day of use.

(d) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

Source. (See Revision Note at part heading for He-P 4032) #6942, eff 2-1-99

He-P 4032.06 Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material. An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material or reagent kits not containing radioactive material used for preparation of radiopharmaceuticals by persons licensed pursuant to He-P 4035 shall be approved if:

(a) The applicant satisfies the general requirements specified in He-P 4030.09;

(b) The applicant submits evidence that:

(1) The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), a biological product license issued by FDA, or a "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by the FDA; or

(2) The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act.

(c) The applicant submits the following information:

(1) The radionuclide;

(2) The chemical and physical form;

(3) The packaging including maximum activity per package; and

(4) The shielding provided by the packaging of the radioactive material contained in the generator or reagent kit.

(d) The label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

(e) The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains;

(1) Radiation safety information on the procedures to be followed and the equipment and shielding to be used in eluding the generator or processing radioactive material with the reagent kit; and

(2) A statement that this generator or reagent kit is approved for use by persons licensed by the DHHS/BRH pursuant to He-P 4035 or under equivalent licenses of the U.S. Nuclear Regulatory Commission, an Agreement State or Licensing State.

(f) The labels, leaflets or brochures required by this He-P 4032.06(d) and (c) are in addition to the label in required by FDA and they may be separate from, or if approved by the FDA, may be combined with

the labeling required by FDA.

Source. (See Revision Note at part heading for He-P 4032) #6942, eff 2-1-99

He-P 4032.07 Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use.

(a) An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed pursuant to He-P 4035 for use as a calibration or reference source or for the uses in Group VI of He-P 4035 may be approved if:

(1) The applicant satisfies the general requirements in He-P 4030.09;

(2) The applicant submits the following radiation safety information for each type of source or device:

a. The radioactive material contained, its chemical and physical form, and amount;

b. Details of design and construction of the source or device;

c. Procedures for, and results of, prototype tests to demonstrate that the source or device shall maintain its integrity under stresses likely to be encountered in normal use and accidents;

d. For devices containing radioactive material, the radiation profile of a prototype device;

e. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

f. Procedures and standards for calibrating sources and devices;

g. Legend and methods for labeling sources and devices for their radioactive content;

h. Instruction for handling and storing the source or device from the radiation safety standpoint.

1. These instructions shall be included on a durable label attached to the source or device or

2. Attached to a permanent storage container for the source or device; or

3. If the instructions are too lengthy for such label, they may be summarized on the label and printed in detail on a brochure which is referenced on the label.

(3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains the following information:

a. The radionuclide;

b. Quantity;

c. Date of assay;

d. A statement that the (name of source or device) is licensed by the DHHS/BRH for distribution to persons licensed pursuant to He-P 4035 group VI or under equivalent licenses of the U. S. Nuclear Regulatory Commission, an Agreement State, or Licensing State; and

e. For sources which do not require long term storage, the label may be on a leaflet or brochure which accompanies the source.

(b) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, the application shall:

(1) Include sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

(2) In determining the acceptable interval for test of leakage of radioactive material, the DHHS/BRH will consider information that includes, but is not limited to:

a. Primary containment (source capsule);

b. Protection of primary containment;

c. Method of sealing containment;

d. Containment construction materials;

e. Form of contained radioactive material;

f. Maximum temperature withstood during prototype tests;

g. Maximum pressure withstood during prototype tests;

h. Maximum quantity of contained radioactive material;

i. Radiotoxicity of contained radioactive material; and

j. Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

Source. (See Revision Note at part heading for He-P 4032) #6942, eff 2-1-99

He-P 4032.08 Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific license to manufacture, assemble, or repair luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under He-P 4031.02(h) may be approved if:

(a) The applicant satisfies the general requirements specified in He-P 4030.09; and

(b) The applicant satisfies the requirements of 10 CFR 32.53, 32.54, 32.55 and 32.56 and 32.101.

Source. (See Revision Note at part heading for He-P 4032) #6942, eff 2-1-99

He-P 4032.09 Licensing the Distribution of Radioactive Material in Exempt Quantities.

(a) An application for specific license to distribute radioactive material other than source or byproduct material to persons exempted from licensing pursuant to He-P 4030.08 may be approved if:

(1) The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

(2) The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(3) The applicant submits copies of prototype labels and brochures and the DHHS/BRH approves such labels and brochures.

(b) The license issued under He-P 4032.09 is subject to the following conditions:

(1) No more than ten exempt quantities provided the sum of the fractions shall not exceed one which may be composed of fractional parts shall be sold or transferred in any single transaction.

(2) Each exempt quantity shall be separately and individually packaged.

(3) No more than ten packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to He-P 4030.03.

(4) The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

(5) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which a. identifies the radionuclide and the quantity of radioactivity, and b. bears the words "Radioactive Material".

(6) In addition to the labeling information required by He-P 4032.09, the label affixed to the immediate container, or an accompanying brochure, shall:

a. State that the contents are exempt from Licensing State requirements;

b. Bear the words "Radioactive Material--Not for Human Use--Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinal, or into Products Manufactured for Commercial Distribution is Prohibited--Exempt Quantities Should Not be Combined"; and

c. Set forth additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

(c) Each person licensed under He-P 4032.09 shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under He-P 4030.03 or the equivalent rules of an Agreement State or Licensing State, and the kinds and quantities of radioactive material transferred.

(d) An annual summary report shall be filed with the DHHS/BRH.

(1) Each report shall state the total quantity of each radionuclide transferred under the specific license;

(2) Each report shall cover the year ending June 30;

(3) Each report shall be filed within 30 days after the end of the quarter; and

(4) If no transfers of radioactive material have been made pursuant to this section during the reporting period, the report shall so indicate.

Source. (See Revision Note at part heading for He-P 4032) #6942, eff 2-1-99

He-P 4032.10 Licensing the Incorporation of Radioactive Material Other than Source or Byproduct Material into Gas and Aerosol Detectors.

(a) In addition to the requirements set forth in He-P 4030.09, an application for a specific license authorizing the incorporation of radioactive material other than source or byproduct material into gas and aerosol detectors to be distributed to persons exempt under He-P 4030.03 shall only be approved if the application satisfies requirements equivalent to those contained in 10 CFR 32.26.

(b) The maximum quantity of radium-226 in each device shall not exceed 0.1 microcurie.

Source. (See Revision Note at part heading for He-P 4032) #6942, eff 2-1-99

He-P 4032.11 Special Requirements for License to Manufacture, Import or Initially Distribute Sealed Sources or Devices Containing Sealed Sources to Persons Having a Specific License.

(a) An application for license to manufacture, import (NARM only) or initially distribute sealed sources or devices containing sealed sources for initial transfer to persons having a specific license to receive such sealed sources or devices shall be approved subject to the following conditions:

(1) The applicant satisfies the general requirements specified in He-P 4030.09; and

(2) The licensee subject to He-P 4032.11 shall not transfer a sealed source or device containing a

sealed source to any person except in accordance with the requirements of He-P 4030.16.

(b) Any manufacture, importer of NARM or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license may submit a request to the DHHS/BRH for evaluation of radiation safety information about its product and for filing an evaluation sheet in the U.S. Department of Health and Human Services "Radioactive Material Reference Manual" or in the U.S. Nuclear Regulatory Commission "Registry of Radioactive Sealed Sources and Devices."

(1) A request for evaluation of a sealed source or device containing a sealed source shall be submitted in duplicate and shall include information required by He-P 4032.11(b)(2) or (3), as applicable, demonstrating that the radiation safety properties of such source or device will not endanger public health and safety or property;

(2) A request for evaluation of a sealed source shall include the following radiation safety information:

a. Proposed uses for the sealed source;

b. Chemical and physical form and maximum quantity of radioactive material in the sealed source;

c. Details of design of the sealed source, radiation and its shielding including blueprints, engineering drawings or annotated drawings;

d. Details of construction of the sealed source including a description of materials used in construction;

e. Radiation profile of a prototype sealed source;

f. Procedures for and results of prototype testing;

g. Details of quality control procedures to be followed in manufacture;

h. A description or facsimile of labeling to be affixed to the sealed source;

i. Leak testing procedures; and

j. Any additional information, including experimental studies and tests, required by the DHHS/BRH to facilitate a determination of the safety of the sealed source, as required by He-P 4030.09.

(3) A request for evaluation of a device containing a sealed source shall include the following radiation safety information:

a. Proposed uses for the device;

b. Manufacturer, model number, chemical and physical form and maximum quantity of radioactivity in the sealed source or sources to be used in the device;

c. Details of design of the sealed source, including blueprints, engineering drawings or

annotated drawings;

d. Details of construction of the sealed source including a description of materials used in construction;

e. Radiation profile of a prototype device;

f. Procedures for and results of prototype testing;

g. Details of quality control procedures to be followed in manufacture;

h. A description or facsimile of labeling to be affixed to the device;

i. Leak testing procedures;

j. A description of potential hazards in installation, service, manufacture, handling, use and operation of the device;

k. Information about installation, service and maintenance procedures;

l. Handling, operating and safety instructions; and

m. Any additional information, including experimental studies and tests, required by the DHHS/BRH to facilitate a determination of the safety of the device as required by He-P 4030.09.

(4) When evaluating a sealed source or device, the DHHS/BRH will apply the radiation safety criteria described in 10 CFR 32.210(d), published January 1, 1993, exclusive of subsequent amendments or editions.

(5) The person submitting a request for evaluation of a product shall manufacture and distribute the product in accordance with:

a. The statements and representations, including the quality control program, described in the request; and

b. the provisions of the evaluation sheet prepared by the DHHS/BRH and submitted to the U.S. Department of Health and Human Services, for filing in the "Radioactive Material Reference Manual" or in the U.S. Nuclear Regulatory Commission, for filing in the "Registry of Radioactive Sealed Sources and Devices."

Source. (See Revision Note at part heading for He-P 4032) #6942, eff 2-1-99

He-P 4032.12 Prohibition. No person shall introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under He-P 4032.12 or equivalent regulations of an Agreement State, the Nuclear Regulatory Commission or Licensing State, except in accordance with a license issued pursuant to He-P 4032.04 or the general license provided in He-P 4030.18.

Source. (See Revision Note at part heading for He-P 4032) #6942, eff 2-1-99